K080923

i-SENS, Inc.
i sens 465-6 Wolgye-dong, Nowon-gu, Seoul 139-845, Korea Tel. 82-2-916-6191

510(k) SUMMARY

(As required by 21.CFR.807.92)

OCT 17 2008

Type of 510(k): Traditional

Introduction: According to the requirements of 21 CFR.807.92, the following information provides sufficient data to understand the basis for a determination of substantial equivalence.

Submitted By:
i-SENS, Inc.
465-6, Wolgye-dong, Nowon-gu, Seoul, 139-845, Korea
Tel.) ++82-2-916-6191
Fax) ++82-2-942-2514
www.i-sens.com

Contact Person: Dr. Hyun Joon Oh, Phone: +82-33-903-0760. Fax +82-33-748-6191

Date Summary, Prepared: March 18, 2008

Device Name:
Trade name: CareSens Blood Glucose Monitoring System
Common Name: Blood Glucose Test System
Classification Name: Class II, 862.1345 Glucose Blood Tester

Predicate Device: We claim substantial equivalence to the OneTouch® Ultra® from LifeScan, Inc.,

Device Description: CareSens Blood Glucose Monitoring System is an in vitro diagnostic device designed to measure the concentration of glucose in capillary whole blood with CareSens Test Strips. The CareSens II model consists of the CareSens II meter, CareSens test strips, CareSens control solution

510(k) Summary, Continued

(Normal and Middle ranges), check strips, lancing device, lancets, user manual, quick reference guide and a logbook. CareSens POP model consists of the CareSens POP meter, CareSens test strips and lancing device, lancets, user guide, and quick guide.

The test principle is:

CareSens Blood Glucose Monitoring System is an in vitro diagnostic product intended for the measurement of glucose concentration in human blood, based on the glucose oxidase method for glucose determination. Each test strip features an electrode containing the enzyme glucose oxidase. A blood sample is applied to the blood collection area at the tip of the strip and is automatically drawn into the reaction zone, where the glucose oxidase catalyzes the oxidation of glucose to produce gluconic acid. During the reaction, a mediator transfers electrons to the electrode surface and generates a current. The amount of the current is proportional to the amount of glucose present in the blood sample. The test strip employs an electrochemical signal generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the Meter and displayed as your blood glucose result.

Intended Use:

The CareSens II, CareSens POP Meters are used for the quantitative measurement of glucose level in capillary whole blood as an aid in monitoring the effectiveness of diabetes management at home or in clinical settings. CareSens Blood Glucose System is only for testing outside the body (in vitro diagnostic use only). Testing sites include the traditional fingertip along with alternate sites such as forearm, palm, thigh and calf.

510(k) Summary, Continued

CareSens Test Strips work with the CareSens II, CareSens POP meters to quantitatively measure glucose level in capillary whole blood as an aid in monitoring the effectiveness of diabetes management in the home or in clinical settings. CareSens Blood Glucose System is only for testing outside the body (in vitro diagnostic use only). Testing sites include the traditional fingertip along with alternate sites such as forearm, palm, thigh and calf.

CareSens Normal and Middle Control Solutions are a red liquid which is to be used to check that both the CareSens meters and CareSens test strips are working together properly. It contains a known range of glucose as specified on the vial.

Comparison to Predicate Device: The i-SENS, Inc. CareSens Blood Glucose Monitoring System is substantially equivalent to the other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed item, the OneTouch® Ultra® by LifeScan, Inc.

Predicate Device 510(k) number: K024194

Similarities		
Item	**Device**	**Predicate**
Enzyme	Glucose Oxidase	
Measurement principle	Amperometric method	
Test principle	Glucose Oxidase chemical reaction. The instrument measures the extent of current cause by presence of glucose in sample.	
Intended use	The test strips work with the device to quantitatively measure glucose in whole blood. The test Strips are for *in vitro* (i.e., outside	

510(k) Summary, Continued

Similarities:

	the body) diagnostic use only.
Coding System	Button
Sample	Fresh capillary whole blood
Electrode	Carbon
Calibration	Plasma-equivalent
Test Time	5sec
Test Range(mg/dL)	20~600
Glucose unites	Either mg/dL or mmol/L
Checking the system	Control solution
Alternate Site Capability	Yes
Operating Humidity	10~90%

Data demonstrating Substantial equivalence: The clinical data demonstrates the performance of the CareSens Blood Glucose Monitoring System well with the laboratory glucose reference test equipment. All predetermined acceptance criteria were satisfied. The data also demonstrate that the CareSens Blood Glucose Monitoring System is substantially equivalent to the predicate device.

Conclusion: CareSens Blood Glucose Monitoring System is substantially equivalent to the following predicate device system: K024194
- LifeScan, Inc. OneTouch® Ultra® Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

I-Sens, Inc.
c/o Hyun Joon Oh
Division Manager, Quality Assurance
465-6 Wolgye-Dong, Nowon-Gu
Seoul, Republic of Korea 139-845

OCT 17 2008

Re: k080923
Trade Name: CareSens Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: August 25, 2008
Received: August 25, 2008

Dear Hyun Joon Oh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (k080923):

Device Name: CareSens Blood Glucose Monitoring System

Indication For Use: The CareSens II, CareSens POP Meters are used for the quantitative measurement of glucose level in capillary whole blood as an aid in monitoring the effectiveness of diabetes management at home or in clinical settings. CareSens Blood Glucose System is only for testing outside the body (in vitro diagnostic use only). Testing sites include the traditional fingertip along with alternate sites (forearm, palm, thigh and calf)

CareSens Test Strips work with the CareSens II, CareSens POP meters to quantitatively measure glucose level in capillary whole blood as an aid in monitoring the effectiveness of diabetes management in at home or in clinical settings. CareSens Blood Glucose System is only for testing outside the body (in vitro diagnostic use only). Testing sites include the traditional fingertip along with alternate sites (forearm, palm, thigh and calf)

CareSens Normal and Middle Control Solutions are a red liquid which is to be used to check that both the CareSens meters and CareSens test strips are working together properly. It contains a known range of glucose as specified on the vial.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use X (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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